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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,732	12/20/2004	Robert M Lorence	18025-PCTUS	3190
7590		01/29/2008		
Lewis J. Kreisler Legal Department 930 Clopper Road Gaithersburg, MD 20878			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,732	Applicant(s) LORENCE, ROBERT M	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 12, 17, 21-23, 26-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 31, 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 12, 17, 21-23, 26-30, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.
2. Claims 1-6, 9, 12, 17, 21-23, 26-32, and 34 are pending in the application.
3. In the prior action, mailed on June 29, 2007, claims 1-6, 9, 12, 17, 21-23, 26-32, and 34 were pending; with claims 31 and 32 withdrawn from examination; and claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 rejected.
4. In the Response of November 29, 2007, arguments were made in traversal of the rejections.
5. Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 are under consideration.
6. Because this action raises new grounds of rejection, it is made Non-Final.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on September 17, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(New Rejection)** Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim depends from cancelled claim 16. As such, it is not clear what method is being further described according to the limitation of claim 17. The claim is therefore indefinite.

For the purposes of this action, the claim is treated as depending from claim 1.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 6, 9, 12, 17, 21-23, 26-30, 34 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorence R (hereinafter "Lorence A", WO 99/18799A1) in view of Lorence R. (hereinafter "Lorence B," WO 94/25627A1). Applicant's arguments with respect to the anticipation of the claims are found persuasive.

In view of the arguments presented, the rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 as obvious under 35 U.S.C. 103(a) over the teachings of the

Lorence references, further in light of the teachings of Curtis et al. (U.S. 7083794) and Castracane et al. (U.S. 2005/0074901).

With respect to obviousness rejections, the Applicant provides three arguments in traversal.

First, the Applicant argues that none of the cited references teach the feature of the claimed methods requiring that the desensitization steps involve administration of two or more sequential desensitization doses, wherein the amount of the virus in each of the second and subsequent desensitization doses is greater than the amount of the virus in the preceding doses. This argument is found persuasive in part. However, the rejection has been restated as indicated above such that the Lorence references are now being read in view of additional knowledge available to those of ordinary skill in the art.

The teachings of the Lorence references have been described, in part, previously. It is noted that, in addition to teaching the use of a desensitization dose, the Lorence A reference also indicates that after successive administrations of the virus resulted in increasingly reduced reactivity of the subjects to the virus. Page 66. While the teachings in this page are directed to reduced reactivity seen both after the initial desensitization dose, and the after successive therapeutic doses, other teachings indicate that it was known in the art that the administration of increasing amounts of various compounds results in improved tolerance to the compounds. See e.g., Curtiss, page 1 paragraph [0011]; and Castracane, column 18 lines 32-35. In view of these teachings, it would have been obvious to those of ordinary skill in the art to have modified the teachings of the Lorence references to include additional desensitization doses of successively increasing amounts. Thus, while the teachings of the Lorence references do not actually teach the

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use of such doses as required by the claims, the teachings of the references do, in light of the knowledge in the art (as indicated by the teachings of e.g. Curtiss and Castracane) that administration of increasing doses of compounds induces tolerance, render the use of such a method obvious.

In view of this restatement of the rejection, the Applicant's argument is not found persuasive.

Second, the Applicant argues that the Examiner's assertion that it was within the skill of those in the art to determine the effective dosages and schedules for administration of the viruses is not a proper basis for finding the claimed methods obvious. Applicant asserts that the Examiner "is required to show that one skilled in the art at the time of invention would have been motivated to administer a negative-stranded virus to a subject as is particularly claimed."

It is noted that the dosing and administration of the claimed methods falls within the bounds of those disclosed by the teachings of the Lorence A reference. See e.g., pages 30-32. Moreover, as was indicated by the teachings of each of Lorence references (see e.g., Lorence A, page 31, beginning of first full paragraph; and Lorence B, page 11 lines 28-30), it was known in the art to adjust the dosages and form of administration based on a number of factors. Where such optimization requires only routine experimentation, it is appropriate to reject the claims as obvious. See e.g., MPEP 2144.05 (esp., 2144.05 II.A.). Thus, the Examiner is not required to show teachings in the art relating to the specifics of the claimed methods where such limitations would have been obvious through routine optimization of known or suggested methods. As the

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Applicant presents no argument or evidence that these dosages or modes of administration are critical to the claimed method. This argument is therefore not found persuasive.

Finally, the Applicant traverses the rejection on the bases that the teachings of the specification show that the claimed invention ‘unexpectedly results in less toxicity as compared to "single-step desensitization.”’ The Applicant asserts that the Examiner has not pointed to anything known in the art at the time of invention that would have suggested or predicted the resulting significant reduction in toxicity. Applicant’s attention is drawn to the teachings of page 69 of Lorence A. The paragraph entitled “Desensitization” indicates that after successive administrations, patients became more and more tolerant to the administered virus. Moreover, other teachings in the art indicate that it was known in the art that successive administration of increasing dosages of various compounds results in increasing tolerance in the treated subjects. See e.g., Curtiss, page 1 paragraph [0011]; and Castracane, column 18 lines 32-35. In view of these teachings, it would have been obvious to those of ordinary skill in the art that decreased sensitivity to NDV could be achieved through the administration of multiple desensitization doses of the virus in increasing amounts. As such, the demonstration by the Applicant that such increased desensitization was achieved in through use of this tactic is not an unexpected result, as those of ordinary skill in the art would have expected that the use of such a mode of tolerance induction would provide such improved desensitization. This argument is therefore also not found persuasive.

For these reasons, and for the reasons of record, the rejection is maintained.

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12. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 34 were rejected under 35 U.S.C. 102(a) as anticipated by Pecora et al. (J. Clinical Oncology May 2002, Vol. 20, no. 9, pp. 2251-2266) or, in the alternative, under 35 U.S.C. 103(a) as obvious over in view of Lorence R. (WO 94/25627A1). For substantially the same reasons as described above with respect to the rejection over Lorence A in view of Lorence B (Lorence R, WO 94/25627A1), this rejection is also restated as an obviousness rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of Pecora in view of Lorence B, and further in light of the teachings of Curtis and Castracane.

Like the Lorence A reference above, Pecora also shows that patients showing increasing tolerance to the virus after successive administrations. Page 2255, first full paragraph of right column. Thus, it would have been obvious to those of ordinary skill in the art to improve the tolerance of the patients to the virus with additional desensitization administrations as was used in the art to induce tolerance to other compounds.

The Applicant traverses this rejection on the same grounds as asserted with respect to the rejection over Lorence A and B above. For the same reasons as indicated above with respect to that rejection, the Applicant's arguments are not found persuasive over the restated rejection.

13. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 34 are still rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorence R (WO 0062735A2) in view of Lorence R. (WO 94/25627A1). For substantially the same reasons as described above with respect to the rejection over Lorence A in view of Lorence B (Lorence R, WO 94/25627A1), this rejection is also restated as an obviousness rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the

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teachings of Lorence R (WO 0062735A2, hereinafter "Lorence C") in view of Lorence B, and further in light of the teachings of Curtis and Castracane.

Like the Lorence A reference above, Lorence C also shows that patients showing increasing tolerance to the virus after successive administrations. Page 69. In fact, this reference specifically indicates that increased desensitization was also found between successive therapeutic doses. Thus, it would have been obvious to those of ordinary skill in the art to improve the tolerance of the patients to the virus with additional desensitization administrations as was used in the art to induce tolerance to other compounds.

The Applicant traverses this rejection on the same grounds as asserted with respect to the rejection over Lorence A and B above. For the same reasons as indicated above with respect to that rejection, the Applicant's arguments are not found persuasive over the restated rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 6, 26, 27, 29, 30, and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-12 of the copending Application No. 10,547,654 in view of Lorence R. (WO 94/25627A1). This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the copending claims 1-8 and 11-12 of the copending Application No. 10,547,654, in view of the teachings of Lorence R (WO 0062735A2-the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

The rejection is extended to claims 9, 12, 17, 21-23, and 28 in view of the reliance on the teachings of the Lorence C reference as described above, and in the prior actions. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments, and in view of the restatement of the present rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 6, 9, 12, 17, 21-29, 30, 34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 14-15, 18-19 of copending Application No. 10,548,057 in view of Lorence R. (WO 94/25627A1). This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the copending claims 1-19 of copending Application

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No. 10,548,057, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments, and in view of the restatement of the present rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. **(Prior Rejection- Restated and Maintained)** Claims 1-5, 29 and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 16-17 of copending Application No. 10,700,143 in view of Lorence R. (WO 94/25627A1). This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the copending claims 1, 5-17 of copending Application No. 10,700,143, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments, and in view of the restatement of the present rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. **(Prior Rejection- Restated, Reinstated, and Maintained)** Claims 1-4 and 34 were previously rejected provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 118, 119, 120, 133, 149, 150 of copending Application No. 10,167,652 in view of Lorence R. (WO 94/25627A1). This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the copending claims 118, 119, 120, 133, 149, 150 of copending Application No. 10,167,652, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

It is noted that the rejection over the claims of copending application 10/167652 were previously withdrawn. However, the arguments over which the rejection were withdrawn (re: the requirement for the two step desensitization) are not found persuasive for the reasons indicated in response to the arguments over the obviousness rejections above, and in view of the restatement of the present rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. **(Prior Rejection- Restated and Maintained)** Claims 1-5 and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 157, 166, 174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,958,809 in view of Lorence R. (WO 94/25627A1). This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the copending claims 157, 166,

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174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,985,809, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments, and in view of the restatement of the present rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. **(Prior Rejection- Restated, Reinstated, and Maintained)** Claims 1-5 and 34 were previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,056,689 in view of Lorence R (WO 94/25627A1), Applicant's arguments, filed on May 03, 2007, with respect to reference the ODP rejection of said claims have been fully considered and are persuasive. This rejection is restated as a rejection of claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 over the teachings of the claims 1-27 of U.S. Patent No. 7,056,689, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane.

It is noted that the rejection over the claims of patent were previously withdrawn. However, the arguments over which the rejection were withdrawn (re: the requirement for the two step desensitization) are not found persuasive for the reasons indicated in response to the

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arguments with respect to the obviousness rejections above, and in view of the restatement of the present rejection.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648